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Improving Safe Use of Medications During Pregnancy: The Roles of Patients, Physicians, and Pharmacists

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Abstract

Our study sought to explore the actual and potential roles of patients, physicians, and pharmacists, as well as their shared challenges and opportunities, in improving the safety of medication use during pregnancy. We conducted virtual focus groups with 48 women and in-depth interviews with nine physicians and five pharmacists. Qualitative analysis revealed that all three groups of participants reported “playing it safe,” the need for an engaged patient making informed decisions, challenges surrounding communication about pregnancy status, and a lack of patient-centric resources. Patients, physicians, and pharmacists are highly motivated to protect developing babies from potential harms of medication use during pregnancy while maintaining the patient’s health. Strategic messaging could maximize the effectiveness of these interactions by helping physicians discuss the benefits and risks of medication use during pregnancy, pharmacists screen for pregnancy and counsel on medication safety, and patients using medications to share pregnancy intentions with their providers pre-pregnancy.

Keywords

doctor–patient; nurse–patient; communication; decision making; patient; education; information seeking; health; pregnancy; reproduction; qualitative; triangulation; United States

Medication use during pregnancy is becoming more common, and its impact on maternal and fetal health is a growing concern in the public health and clinical care arenas. Recent studies have shown that most pregnant women across developed countries took at least one medication during pregnancy (Lupattelli et al., 2014; Mitchell et al., 2011). One of these

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studies also showed that 70% of women in the United States took at least one medication during the first trimester (Mitchell et al., 2011).

Because pregnant women are not routinely included in premarketing medication studies, information about medication safety during pregnancy is limited. More than 90% of the medications approved by the U.S. Food & Drug Administration (FDA) between 1980 and 2010 that were examined in a study had an undetermined teratogenic risk (Adam, Polifka, & Friedman, 2011). Nonetheless, some medications have been associated with adverse pregnancy outcomes when taken during pregnancy (Briggs, Freeman, & Yaffe, 2008), and it is generally accepted that certain medications can cause serious birth defects if taken during pregnancy (Fisher, Rose, & Carey, 2008; Obican & Scialli, 2011).

The limited availability of information on medication safety during pregnancy underscores the important role that health care providers play as trusted sources of information for women. Of the obstetrician-gynecologists (OB/GYNs) responding to a survey assessing knowledge and resources about the risks of medication use during pregnancy, 90% reported receiving questions from all or many of their pregnant patients about the effects of prescription medication on the fetus; 63% reported that all or many patients had inquired about the fetal effects of over-the-counter medications (M. A. Morgan, Cragan, Goldenberg, Rasmussen, & Schulkin, 2010). OB/GYNs are not the only health care providers who are discussing safe medication use during pregnancy; on the contrary, other types of health care providers including pharmacists are receiving questions from patients regarding drug safety during pregnancy (Crijns et al., 2013; Eisenberg, Stika, Desai, Baker, & Yost, 2010; Goodwin, Rieder, Rieder, & Matsui, 2007; Schwarz et al., 2009). Women of childbearing age commonly believe that health care providers should be responsible for initiating conversations about the risks of medication (Santucci, Gold, Akers, Borrero, & Schwarz, 2010). For such conversations to be effective, participants indicated that they should include reasoning for the health care providers' inquiry about family planning and cover (with repetition) timely, comprehensive, and clear information regarding a medication's potential effect on a fetus. Although research is limited on whether and how much health care providers share information about medication use, evidence suggests that health care providers do not provide contraceptive counseling to the majority of women of childbearing age to whom they prescribe possibly teratogenic medications (Schwarz, Maselli, Norton, & Gonzales, 2005; Schwarz et al., 2012; Schwarz et al., 2013; Schwarz, Postlethwaite, Hung, & Armstrong, 2007). Barriers for care providers include the perception that they have not been taught to recognize which medications are known teratogens (Eisenberg et al., 2010), liability concerns, difficulty interpreting and communicating information for patients in an understandable way, insufficient time to communicate information to patients, and concerns about how patients' anxiety about risks will affect their decisions to use necessary medications (M. A. Morgan et al., 2010; Schwarz et al., 2009).

Pharmacists also play a critical role in medication safety for pregnant women. Pharmacists are easily accessible and are available for consultation at the point of medication dispensing (Damase-Michel, Christaud, Berrebi, Lacroix, & Montastruc, 2009; Samuel & Einarson, 2011). Some literature has shown that pharmacists feel ill-equipped to provide guidance to pregnant women about medication use, are not aware of resources specific to counsel

pregnant women, and often refer the patient back to the prescribing physician without providing consultation (Samuel & Einarson, 2011).

Finally, women also face challenges in patient–provider interactions and decision making around medication use during pregnancy. The increased medicalization of pregnancy and surveillance for a multitude of risks has affected how women interact with the health care system and make decisions for the health of their fetus (Hammer & Burton-Jeangros, 2013). In addition, an increased focus on the fetus as a protected entity in society in combination with pervasive societal perceptions of a pregnant woman's role as caring and monitoring her body for the protection of the fetus further affects women's interactions with providers and decisions around medication use (Lupton, 2012). These cultural trends have shifted the emphasis from the pregnant woman as the primary patient to the health of the fetus, above all. For example, in one study about insulin use to treat gestational diabetes, women reported feeling a "loss of control" over decisions in their care, and perceived the use of "scare tactics" in interactions with providers (Figueroa Gray, Hsu, Kiel, & Dublin, 2017).

The interactions between a woman, her physicians, and her pharmacist have the potential to influence her use of prescription and over-the-counter medications during pregnancy, yet barriers exist to these interactions. A 2015 expert panel convened by maternal and child health leaders in the United States highlighted a research gap and the need for specific approaches to improve patient–provider communication around the risks of medication use and improved, shared decision making (Riley, Cahill, Beigi, Savich, & Saade, 2016). To address this gap, we conducted formative research with each of these three groups—patients, physicians, and pharmacists—to learn more about their knowledge, attitudes, behaviors, and decision-making processes that factor into these interactions, as well as their access to information and resources about medication safety during pregnancy.

The primary aim of the exploratory study reported in this article was to triangulate the findings from formative research across these three participant groups to develop understanding of the potential and actual roles of each group as well as their shared challenges and opportunities in improving medication safety during pregnancy.

Method

Literature Review

At the outset, our partners at the March of Dimes Foundation conducted a literature search in PubMed that identified a total of 37 peer-reviewed articles published in English between 2004 and 2014, which were subsequently retrieved, reviewed, abstracted, and summarized. The knowledge gaps identified through the literature review led us to select qualitative methods—specifically focus groups and in-depth interviews—as it was apparent to us that filling them would require a level of detail in responses that is difficult to achieve via large surveys, especially without evidence to guide the development of response categories (D. Morgan, 1998). The literature review findings informed our selection of women, physicians, and pharmacists as participants as well as our segmentation design within each of these three participant groups. Finally, the literature review findings facilitated our development of an

assortment of research questions to guide our data collection with each participant group; examples of specific research questions by group are shown in Table 1.

Participants and Procedures

In 2014 to 2015, we conducted interviews with nine physicians and five pharmacists, as well as six virtual focus groups with 48 women who took medication while pregnant or planning a pregnancy. All interviews and focus groups were conducted in English within the United States. All participants were recruited by a professional recruitment firm that provides tailored recruitment by using their proprietary online panels and following up with telephone recruiting. The recruiter used screening questionnaires developed by the study team to identify eligible participants representing a mix of selected characteristics (i.e., provider specialty, geographic region, demographics). Participants received a monetary incentive as a thank you for their time.

Physician and pharmacist interviews—We obtained a purposive sample of physicians who had been practicing medicine for at least 2 years and who had prescribed medications to a woman of reproductive age in the past 3 months. The sample included three general practitioners or family medicine doctors, three psychiatrists, and three allergists or pulmonologists. These specialties were chosen because those providers often treat conditions common to women of childbearing age that frequently require prescriptions for condition management. However, these specialists may lack the awareness of issues of medication safety in pregnancy and may be less comfortable speaking about them with patients (in contrast to OB/GYNs and other health care providers who regularly see pregnant women). We obtained a purposive sample of licensed pharmacists who had been practicing for at least 2 years, and who reported providing medication counseling to patients at least 20 hours per week in a retail setting. A trained interviewer conducted each interview via telephone using a semistructured interview guide. The interviews were audio-recorded, and a notetaker recorded key responses. Each interview lasted approximately 45 minutes and was professionally transcribed.

Patient virtual focus groups and interviews—We conducted six virtual focus groups with women (18–44 years old) in the United States. The use of virtual focus groups, in lieu of traditional focus groups, offered important benefits to the study, including giving participants more privacy and anonymity, which we believed may be important to women with chronic or acute conditions or who may perceive taking medication during pregnancy as a sensitive topic. To capture different perspectives on and experiences with medication use during pregnancy, the virtual focus groups were segmented by pregnancy status and medication type (see Table 2).

A trained moderator used a semistructured moderator guide to lead participants in an open discussion. We partnered with an online focus group vendor to conduct realtime, live-chat sessions, which allowed the moderator to post questions and probes and allowed participants to type responses visible to the moderator and all other participants. Each group lasted about 60 to 90 minutes, and transcripts were produced instantaneously.

To supplement the virtual focus groups and obtain a more in-depth perspective on themes identified in the focus groups, we conducted follow-up telephone interviews with a subset of participants. We selected two participants from each focus group who provided an interesting perspective or exemplified a major focus group finding and invited these women to participate in one-on-one telephone follow-up interviews. All 12 invited participants agreed to participate in the follow-up calls. Each interview lasted approximately 20 to 30 minutes.

Ethical Issues

All data collection was approved by RTI International's Institutional Review Board. In accordance with the Paperwork Reduction Act, data collection with women was approved by the Office of Management and Budget. All participants consented prior to participation in data collection. Specifically, for virtual focus groups, participants were invited into a virtual waiting room prior to the start of each live-chat session where the moderator posted the informed consent form, which described the purpose of the study; informed participants that their participation is voluntary; and informed them that their identity and anything they say will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. If willing to participate, participants checked a box indicating their consent that then linked them into the live-chat session. The same information was provided to telephone interview participants as part of obtaining their verbal consent prior to beginning the interview. All participants had the option of refusing to answer any questions or terminating their involvement in the study at any time, without penalty.

Data Analysis

A crux of our analytic methodology was using *triangulation* between the three groups to develop an understanding of the roles each group plays in medication safety, as well as the barriers and facilitators to safer medication use. As a single source would not be able to elucidate the complete picture, we utilized multiple data sources to enrich our understanding of the problem and potential solutions (Denzin, 1978). To conduct this triangulated analysis, two analysts independently reviewed and coded transcripts in NVivo 10.0 qualitative analysis software. Analysts coded responses according to a set of predetermined codes representing key constructs from the research questions and developed and assigned emergent codes for responses that did not fit the preexisting coding scheme (Krueger & Casey, 2000). To determine interrater reliability, the analysts double coded the first two transcripts from each set to ensure that the data were coded consistently. Coders compared and reconciled differences. Subsequent to reaching agreement of 90% and above, transcripts were coded by one analyst. Coding reports were produced, and key themes and trends across the virtual focus groups and interviews, participant groups, and, when applicable, specific segments of the participants were identified. The degree of consensus or discordance with particular views was assessed to focus on what the group, rather than individual, thought. After key themes were independently identified for each participant group, the research team examined overlapping themes between the three participant groups to triangulate findings and identify the most salient themes across all three groups. Per Krueger and Casey's (2000) recommendations, we also examined the extent to which what we knew and what we

suspected was confirmed or challenged by our data as well as what we observed that was new and not previously suspected.

Results

Sample Characteristics

Physicians—The nine physicians interviewed practiced in seven different U.S. states. Six were male and three were female. The majority of the physicians ($n = 7$) had been practicing for more than 10 years post-residency. The physicians worked in a variety of health care settings including community health centers, hospitals, small group practices, or offices specific to their specialty.

Pharmacists—The five pharmacists interviewed resided in five different U.S. states and all were male. The majority of the pharmacists ($n = 4$) had been practicing for more than 10 years and their experience ranged from 4 years to 35 years of pharmacy practice. All of the pharmacists worked in retail settings, and two mentioned working in both retail and hospital settings.

Patients—As shown in supplemental table, the participants ranged in age from 23 to 44 years. The majority of participants were White (54%), reported a total family income in the US$30,000 to US$75,000 range (52%), and had completed some college education (from 1 to 4 years; 83%). The focus groups included participants from across the United States.

Findings

In this section, we present intersecting themes that emerged from interviews and focus groups with the three participant groups.

“Play it safe. ”—All three participant groups indicated that the safety of the mother and fetus was the top priority in making decisions about medication use during pregnancy, although patients tended to focus more heavily on the safety of the fetus. When prescribing or dispensing medication to pregnant women, physicians and pharmacists choose the safest treatment approach possible during pregnancy for the mother and fetus.

Not surprisingly (Wiley, Cooper, Wood, & Leask, 2015) women reported that they are cautious in their use of medication during pregnancy and are highly motivated to protect their babies. Most women reported that they would not take medication during pregnancy if risks to the fetus are unknown or if there is conflicting information about potential serious risks to the fetus. For example, one participant explained, “If there’s no risk information, then I don’t take the medication. It’s not worth risking the little one. I’d value my doctor’s opinion, but I don’t want to cause life-long damage to the baby.” Similarly, another woman indicated that “I would never take a medication without being very clear on possible side effects for my baby, and if it’s some newer medication without much feedback information other than clinical trials, I would probably not take it.” Women who reported less severe conditions, particularly those with mild/moderate depression, spoke of using alternative or homeopathic medications or therapies to replace their prescribed medications. As one interview participant who was taking medication for depression made a comment that was

representative of women's focus on the safety of the fetus said, "If I have any doubts about something, there is probably some reason behind it. Rather than gambling, why not just play it safe? It's more about focusing on the baby's health."

Physicians said they strive to provide the safest management of medication for pregnant women. This management may involve tapering patients off a drug (a known teratogen), ramping up a drug (e.g., if it prevents an acute episode during pregnancy), or switching to a different drug (e.g., with more data about its use and effects during pregnancy). As one allergist explained,

> Less is more. I try to do the most benign treatments, nasal saline irrigation and maybe a first-generation, over-the-counter antihistamine that's [FDA] Category B [no risks identified for the fetus based on animal studies] or an intranasal steroid that's category B. If they're comfortable enough just with the saline rinse, that's what I suggest during the first trimester.

Pharmacists were also cautious when filling and discussing prescriptions with pregnant women. Pharmacists perceived their role as critical for double checking what physicians prescribe. One pharmacist explained,

> I see myself as the safety monitor for the patient and to make sure that when the patient is taking those medications … they should be safe for her and if there is concern I will make sure that she knows about it. If there's some significant danger to her or to the fetus I will contact the patient directly.

An engaged patient—All three participant groups described the need for an active, engaged patient to participate in the decision-making process.

In many cases, women said they were the ones to initiate discussions with providers about medication use in pregnancy and that they were left to educate themselves about the risks and benefits of the medications. Women trusted their OB/GYNs and looked to them as good resources; nevertheless, the women in our study believed that making the final decisions was up to them. For example, one interview participant taking medication for depression said,

> What's funny is I just saw [my doctor], and after the fact, I was surprised she didn't bring it up although I didn't bring it up either. I should probably call and ask. I think it would probably be better to reduce [my dosage] before I become pregnant.

Many women noted that initiating discussions with their physicians, doing their own research, and making complex decisions about medication use during pregnancy were, in the end, their responsibility.

Because making decisions about the risks and benefits of medication use is complex, physicians reported talking through decisions with their patients so that each patient could make the best decision for her situation. One physician explained the importance of collaborative decision making:

> In general, just again, very collaborative, so that's the way the philosophy of the clinic has been because there's a lot of patient interaction … They're more

> involved. That seems to work out better, better compliance with them being more interactive in the whole process. So it gives them more control.

Pharmacists reported that their role was to provide information about the potential risks of specific medications during pregnancy and to encourage patients to speak with their physicians. Although pharmacists provide information about medications' potential risks, they believe the patient should consult her physician to discuss the risks and benefits of her treatment plan. One pharmacist said,

> Most of the time I tell them they should ask their doctor before they take anything … If it's a drug that I know is fine, then I will tell them it is fine. If it is borderline, I'd say, "I wouldn't take it until you can talk to your doctor."

Patient/provider communication about pregnancy status—All three participant groups described that, ideally, women, their prescribing physicians, and the dispensing pharmacists should be aware of the patient's pregnancy status or intention to become pregnant, and discuss the best course of treatment based on that status. However, the participants reported challenges in the practicality of this approach.

Many women viewed the time prior to pregnancy as the optimal time to develop a treatment plan, but few were actually talking to their physicians in the preconception period.

Although women said that they would like to begin discussions with their physicians prior to pregnancy and discontinue medication or change dosages before becoming pregnant, in actuality, many reported they would not have these discussions until they find out they are pregnant. One woman planning a pregnancy said,

> I think about it all the time and I have just told myself as soon as I know I am pregnant will be the time I stop my medication. I do plan on having open communication about everything with my OB/GYN and if I have problems [I'm] hoping that they can help suggest something.

Physicians reported that they ask about a patient's pregnancy status at the time that they prescribe the medication. Some physicians screen their patients for pregnancy or pregnancy intention and factor this in when prescribing potential teratogens. However, the physicians we interviewed reported a low percentage of pregnant patients in their practices. Although our sample may not be generalizable, it is important to note that some specialists may not frequently treat pregnant women or that the physicians' awareness of pregnancy status among their patients may be low.

Most pharmacists reported that there is not a standard method of assessing pregnancy status or intention if the patient does not disclose her status. Furthermore, some pharmacists reported being uncomfortable asking a woman her pregnancy status directly during a routine interaction. Many of the pharmacists interviewed indicated that their pharmacy computer systems do not have a systematic way of tracking pregnancy status, and especially of tracking pregnancy intention.

Lack of patient-centric educational materials—In general, women reported wanting more specific information from multiple sources about potential harm to the baby so they could make the best decisions based on all the available information. Overwhelmingly, women reported that their OB/GYNs were trusted sources of expert opinion and recommendations about medication use during pregnancy. Patients seemed most interested in having as much detailed information as possible on the risks associated with medication use during pregnancy. As one woman planning a pregnancy explained,

> I wish my doctor would give me information or a print-out with all of the information so I'd know about all the possible side effects. I've asked him this before but he's always rushed … I want him to tell me all the possible side effects in the long run, not just for my child but for me too.

However, when counseling pregnant women about the risks and benefits of a medication, many physicians reported sharing materials with patients that were meant for clinicians with no translation for lay audiences. In general, physicians mentioned FDA categories as the major indicator of a drug's safety during pregnancy, not only relying on them for their own information but also using them in an attempt to help patients understand risks. In the interest of giving patients all the available information, several providers commented that they will give information that they receive about a drug directly to their patients, even if the resource is targeted to physicians and may be difficult for patients to interpret.

When dispensing medications to pregnant women, pharmacists reported printing a handout with information, either from the drug manufacturer's website or the pharmacy's information system, to aid verbal counseling. Two pharmacists mentioned that they did not distribute any educational materials about a drug besides the package insert.

Discussion

Ultimately, patients, their physicians, and their pharmacists should share responsibility for ensuring medication safety during pregnancy. Maternal and fetal health could be endangered if the members of any or all of these three participant groups rely too heavily on the others to make sure that risks are identified, communicated, and carefully balanced with benefits before usage. For example, safety could be compromised if a physician relies on his or her patient to proactively mention that she is planning a pregnancy and the patient does not initiate the conversation because she does not realize that her medication might be teratogenic. Similarly, harm could result if a specialist who commonly prescribes medications to women of childbearing age does not screen for pregnancy status and the patient's pharmacist assumes that the physician would not have prescribed the medication if the women were pregnant. Avoiding these kinds of issues with diffusion of responsibility will require a concerted, collaborative effort on the part of all three groups of participants.

Findings from this study support and expand upon previous literature. Previous research exploring patient–provider communication about medication safety during pregnancy elucidated barriers facing patients, physicians, and pharmacists (Eisenberg et al., 2010; Figueroa Gray et al., 2017; Hammer & Burton-Jeangros, 2013; M. A. Morgan et al., 2010; Obican & Scialli, 2011; Santucci et al., 2010; Schwarz et al., 2009). Our exploratory study

delved deeper into some of those barriers, with special attention to identifying shared challenges affecting the interactions of these three participant groups. Fortunately, we found that, despite the barriers to doing so, patients, physicians, and pharmacists are highly motivated to increase medication safety during pregnancy. However, that motivation needs to be coupled with careful planning; coordination; and access to effective informational resources to yield the desired outcome.

By working together to develop a treatment plan prior to pregnancy, patients and their physicians can ensure that there is adequate time to consider potential benefits and risks and to engage other providers in the decision-making process as appropriate. Technology can be harnessed to facilitate coordination across the health care team. For example, by systematically documenting pregnancy status (including planning or intention to become pregnant) and the medication-related decision-making processes in electronic health records and pharmacy information systems, physicians and pharmacists can more easily ensure that medications are being prescribed and dispensed in the safest manner possible. The quality and utility of the information being used in these critical decisions about medication use during pregnancy is paramount; physicians and pharmacists must have access to comprehensive resources that meet their clinical needs as well as easily understandable resources for patients so that they can work as partners to make the best decisions.

Finally, we learned that health care providers have been not only relying on the FDA pregnancy categories to inform their own understandings of medication risks but also using them to inform patients' decision making despite potential difficulties that both groups may face in interpreting this information. Of note, during the process of our formative research, the FDA announced longawaited changes to pregnancy and lactation labeling regulations for prescription medications and biological products (FDA, 2016). Years of criticism of the letter categories had revealed them to be overly simplistic and often misinterpreted as a gradation of risk rather than as an accounting of the balance of risk and benefit, as they were originally intended (Kweder, 2008). The discontinuation of these letter categories (occurring in a phased approach over several years; FDA, 2016) will require physicians to adapt to a new label format and determine how best to relay this content when counseling their patients.

Practice Implications

As emphasized in the 2015 expert panel (Riley et al., 2016), there is a major research gap around specific approaches to improve patient–provider communication about risks of medication use. Based on our research, we present suggestions for strategic messaging to all three participant groups from this study. For patients, we suggest developing messages alerting women of childbearing age to the importance of starting the process of becoming informed about the safety of medication use during pregnancy prior to conception. These messages should empower women by encouraging them to speak with their health care providers in addition to consulting reputable sources (e.g., patient information inserts provided with medications) independently to learn about the potential risks of medications they are currently taking. We also suggest messaging that encourages women who are

pregnant or could become pregnant to consistently communicate their pregnancy status and plans to their health care team.

For physicians, we suggest developing messages to prompt them to talk with patients about the risks of taking, stopping, or changing the dosage of a medication while trying to become pregnant or during pregnancy. Given that many pregnancies are unplanned, we also strongly suggest the development of reminders geared at prompting all provider types (i.e., not just OB/GYNs) to discuss issues around medication use during pregnancy with their patients of childbearing age. In addition, we suggest the development of digital applications for providers that include links to patient-centric resources that can be printed, emailed, or sent by text messaging.

Finally, we have suggestions that would help better integrate pharmacists in efforts to improve medication safety. First, we suggest the development of marketing materials and journal publications highlighting the unique and critical role that pharmacists play in medication safety during pregnancy. Second, pharmacists in the retail setting need to be encouraged to take a more active role in screening for pregnancy and advising patients on medication safety both before and during pregnancy. It is important to address the issue interviewees raised about the lack of a systematic way of tracking pregnancy status (e.g., planning a pregnancy, woman of childbearing age—pregnancy status unknown, lactating) in pharmacy computer systems; we suggest working with retail pharmacy chains and pharmacy information system developers to include more options for assessing and documenting pregnancy status. For example, automated telephone systems for refill requests could be programmed to ask all callers whether they are pregnant and if so, how many weeks gestation. Patients' responses would be added to the pharmacy information system and flagged to ensure that an alert is generated prompting a pharmacist to speak with the patient about a medication's risks during pregnancy when they pick up the prescription.

Limitations

The uniqueness of this study is that it triangulated findings between three significant groups involved in medication safety during pregnancy: women, prescribing physicians, and pharmacists. Although the study was strengthened by the triangulation of findings between the three participant groups, the study also faced some limitations. We acknowledge that our sample size was small. The patients included in our purposive sample may not be representative of the larger U.S. population of women of childbearing age in terms of geography and demographic characteristics (e.g., education, income, race), and the types of providers we included are not representative of the universe of health care providers involved in caring for women of childbearing age. Along similar lines, the physicians we interviewed reported that a low proportion of their patient loads were pregnant, meaning that we were asking them to focus on interactions that they have infrequently and/or perceive as infrequent. Also, the pharmacists we interviewed were all males; it is possible that female pharmacists would have different responses. Future research with a larger, more representative sample could be used to understand how widespread these challenges and opportunities are.

Conclusion

Patients, physicians, and pharmacists are highly motivated to protect fetuses from the potential harms of medication use during pregnancy. The interactions women of childbearing age have with their physicians and pharmacists have the potential to influence the decisions they make about medication use. Strategic messaging and improved informational resources could help maximize the effectiveness of these interactions by ensuring that women receive the clear, credible, and comprehensive information about medication risks during pregnancy at the right time and in a manner that facilitates the safest possible management of their health conditions.

Physicians need messaging to facilitate their discussion about medication use in pregnancy with women of childbearing age. Pharmacists need messaging that empowers them to play a more active role in screening for pregnancy and counseling women of childbearing age. Both physicians and pharmacists need improved informational resources to support their interactions with patients. Finally, women need messaging to promote the importance of sharing pregnancy status/intention with their providers.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

Adam MP, Polifka JE, Friedman JM. Evolving knowledge of the teratogenicity of medications in human pregnancy. American Journal of Medical Genetics, Part C: Seminars in Medical Genetics. 2011; 157:175–182. DOI: 10.1002/ajmg.c.30313

Briggs, GG., Freeman, RK., Yaffe, SJ. Drugs in pregnancy and lactation. 8. Philadelphia: Lippincott Williams & Wilkins; 2008.

Crijns I, Mantel-Teeuwisse A, Bloemberg R, Pinas E, Straus S, de Jong-Van den Berg L. Healthcare professional surveys to investigate the implementation of the isotretinoin Pregnancy Prevention Programme: A descriptive study. Expert Opinion on Drug Safety. 2013; 12:29–38. [PubMed: 23163396]

Damase-Michel C, Christaud J, Berrebi A, Lacroix I, Montastruc JL. What do pregnant women know about non-steroidal anti-inflammatory drugs? Pharmacoepidemiology and Drug Safety. 2009; 18:1034–1038. [PubMed: 19634118]

Denzin, NK. Sociological methods. New York: McGraw-Hill; 1978.

Eisenberg DL, Stika C, Desai A, Baker D, Yost KJ. Providing contraception for women taking potentially teratogenic medications: A survey of internal medicine physicians' knowledge, attitudes and barriers. Journal of General Internal Medicine. 2010; 25:291–297. DOI: 10.1007/s11606-009-1215-2 [PubMed: 20087677]

Figueroa Gray M, Hsu C, Kiel L, Dublin S. "It's a very big burden on me": Women's experiences using insulin for gestational diabetes. Maternal and Child Health Journal. 2017; 21:1678–1688. DOI: 10.1007/s10995-017-2261-8 [PubMed: 28092062]

Fisher B, Rose NC, Carey JC. Principles and practice of teratology for the obstetrician. Clinical Obstetrics and Gynecology. 2008; 51:106–118. DOI: 10.1097/GRF.0b013e318161d2c8 [PubMed: 18303504]

Goodwin J, Rieder S, Rieder MJ, Matsui D. Counseling regarding pregnancy-related drug exposures by family physicians in Ontario. Canadian Journal of Clinical Pharmacology/Journal Canadien De Pharmacologie Clinique. 2007; 14:e58–e69. [PubMed: 17314415]

Hammer RP, Burton-Jeangros C. Tensions around risks in pregnancy: A typology of women's experiences of surveillance medicine. Social Science & Medicine. 2013; 93:55–63. [PubMed: 23906121]

Krueger, RA., Casey, MA. Focus groups: A practical guide for applied research. 3. Thousand Oaks, CA: Sage; 2000.

Kweder SL. Drugs and biologics in pregnancy and breastfeeding: FDA in the 21st century. Birth Defects Research Part A: Clinical and Molecular Teratology. 2008; 82:605–609. DOI: 10.1002/bdra.20500 [PubMed: 18704917]

Lupattelli A, Spigset O, Twigg MJ, Zagorodnikova K, Mardby AC, Moretti ME, Nordeng H. Medication use in pregnancy: A cross-sectional, multinational web-based study. American Journal of Obstetrics and Gynecology. 2014; 4(2):e004365.

Lupton D. "Precious cargo": Foetal subjects, risk and reproductive citizenship. Critical Public Health. 2012; 22:329–340.

Mitchell AA, Gilboa SM, Werler MM, Kelley KE, Louik C, Hernandez-Diaz S, National Birth Defects Prevention Study. Medication use during pregnancy, with particular focus on prescription drugs: 1976–2008. American Journal of Obstetrics and Gynecology. 2011; 205(1):51.e51–51.e58. DOI: 10.1016/j.ajog.2011.02.029 [PubMed: 21514558]

Morgan, D. The focus group guidebook. Thousand Oaks, CA: Sage; 1998.

Morgan MA, Cragan JD, Goldenberg RL, Rasmussen SA, Schulkin J. Obstetrician-gynaecologist knowledge of and access to information about the risks of medication use during pregnancy. Journal of Maternal-fetal & Neonatal Medicine. 2010; 23:1143–1150. DOI: 10.3109/14767051003653252 [PubMed: 20218819]

Obican S, Scialli AR. Teratogenic exposures. American Journal of Medical Genetics, Part C: Seminars in Medical Genetics. 2011; 157:150–169.

Riley LE, Cahill AG, Beigi R, Savich R, Saade G. Improving safe and effective use of drugs in pregnancy and lactation: Workshop summary. American Journal of Perinatology. 2016; 34:826–832. DOI: 10.1055/s-0037-1598070

Samuel N, Einarson A. Medication management during pregnancy: Role of the pharmacist. International Journal of Clinical Pharmacy. 2011; 33:882–885. DOI: 10.1007/s11096-011-9560-8 [PubMed: 21915759]

Santucci AK, Gold MA, Akers AY, Borrero S, Schwarz EB. Women's perspectives on counseling about risks for medication-induced birth defects. Birth Defects Research, Part A: Clinical and Molecular Teratology. 2010; 88:64–69. DOI: 10.1002/bdra.20618 [PubMed: 19637252]

Schwarz EB, Maselli J, Norton M, Gonzales R. Prescription of teratogenic medications in United States ambulatory practices. American Journal of Medicine. 2005; 118:1240–1249. [PubMed: 16271908]

Schwarz EB, Parisi SM, Handler SM, Koren G, Cohen ED, Shevchik GJ, Fischer GS. Clinical decision support to promote safe prescribing to women of reproductive age: A cluster-randomized trial. Journal of General Internal Medicine. 2012; 27:831–838. [PubMed: 22297687]

Schwarz EB, Parisi SM, Handler SM, Koren G, Shevchik G, Fischer GS. Counseling about medication-induced birth defects with clinical decision support in primary care. Journal of Women's Health. 2013; 22:817–824.

Schwarz EB, Postlethwaite DA, Hung YY, Armstrong MA. Documentation of contraception and pregnancy when prescribing potentially teratogenic medications for reproductive-age women. Annals of Internal Medicine. 2007; 147:370–376. [PubMed: 17876020]

Schwarz EB, Santucci A, Borrero S, Akers AY, Nikolajski C, Gold MA. Perspectives of primary care clinicians on teratogenic risk counseling. Birth Defects Research, Part A: Clinical and Molecular Teratology. 2009; 85:858–863. DOI: 10.1002/bdra.20599 [PubMed: 19591115]

U.S. Food & Drug Administration. Pregnancy and lactation labeling (drugs) final rule. 2016 Mar 23. Retrieved from http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm

Wiley KE, Cooper SC, Wood N, Leask J. Understanding pregnant women's attitudes and behavior toward influenza and pertussis vaccination. Qualitative Health Research. 2015; 25:360–370. [PubMed: 25246330]

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Table 1

Selected Formative Research Questions by Participant Group.

Women	Physicians	Pharmacists
• How does having a chronic or acute condition influence women's knowledge, attitudes, and behaviors regarding medication use during preconception and pregnancy? • What messages do pregnant women and women of childbearing age receive from providers and other sources? • How do pregnant women and women of childbearing age weigh risks and benefits of medication use during pregnancy, considering both the baby's health and their own health? • Who do women perceive is their primary point of contact for questions about medication use during pregnancy?	• What resources and tools are health care providers aware of and which resources and tools do they use? How do these resources and tools vary by practice type? • What are the most common concerns pregnant women and women of childbearing age have about medications? • How do health care providers balance the risks and benefits to both mother and fetus? • To what degree are patient preferences factored into the decision-making process? • What do health care providers perceive as their role in counseling/prescribing/ suggesting effective contraception when they prescribe possible teratogens? • Do health care providers screen for intention to become pregnant when prescribing possible teratogens?	• What role do pharmacists play in counseling pregnant women and women of childbearing age about drug safety, including risks and benefits of medication use? • How are pharmacists increasing drug safety for pregnant women and women of childbearing age? • What protocols and information systems do pharmacists have in place to screen for teratogenic risks? • How often are pharmacists asked about the risks of a medication if the customer should become pregnant or if she is pregnant? • Does communication between providers and pharmacists change with pregnant women and women of childbearing age when prescribing possible teratogens? • How do pharmacists communicate back to physicians after dispensing or counseling?

Table 2

Virtual Focus Group Segmentation (n = 6 Virtual Focus Groups).

Pregnancy Status	Group No.	Prescription Medication Type
Women aged 18–44 planning to become pregnant in next 1–2 years who …	1	Currently take medication for chronic pain
	2	Currently take an antidepressant
	3	Currently use an asthma medication
Women aged 18–44 who gave birth within the last year who …	4	Took a short-term medication during pregnancy
	5	Took an antidepressant during pregnancy
	6	Used an asthma medication during pregnancy